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on DECEMBER 22, 2008

TOWNSEND and TOWNSEND and CREW LLP

By: Kimberly Heidt

PATENT
Docket No.: 016930-000816US
Client Ref. No.: CJ01656KQ

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Heidrun Engler et al.

Application No.: 10/055,863

Filed: January 22, 2002

For: COMPOSITIONS AND METHODS
FOR ENHANCING DELIVERY OF
THERAPEUTIC AGENTS TO CELLS

Customer No.: 20350

Confirmation No.: 4929

Examiner: Elli Peselev

Art Unit: 1623

REQUEST FOR
RECONSIDERATION OF PATENT
TERM ADJUSTMENT
DETERMINATION UNDER 37
C.F.R. §1.705(b)

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.705(b), Applicants respectfully request reconsideration of the patent term adjustment determination. This request is accompanied by the fee set forth in §1.18(e) and a statement of facts as required under 37 C.F.R. §1.705(b)(2). This request is prompted by the recent court decision in *Wyeth v. Dudas* (Case No. 07-1492, D.D.C. 2008) which held that the periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) overlap only if they occur on the same calendar day or days.

Statement of Facts

Correct Patent Term Adjustment and the Bases Under §1.702 for the Adjustment

The correct patent term adjustment is presently 359 days, not 32 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) mailed on September 29, 2008.

The period of adjustment under 37 C.F.R. §1.702(a) is 216 days (“A delay”).

The period of adjustment under 37 C.F.R. §1.702(b) is to be determined when the instant application issues. The current effective period of adjustment as of December 22, 2008, under 37 C.F.R. §1.702(b) is 319 days (“B delay”). Applicants submit that pursuant to §1.702(b), the total period of adjustment continues from this date, December 22, 2008, the date of the instant petition and concurrent submission of the issue fee payment. Applicants are entitled to additional adjustment days until the date of the patent issuance pursuant to §1.702(b).

The period of adjustment under 37 C.F.R. §1.704(a) is 176 days (“applicant delay”).

The period of adjustment under §1.703(f) is 359 days (“A delay” + “B delay” – “applicant delay”).

The Relevant Dates as Specified in 37 C.F.R. §§1.703(a)-(e) & the Adjustment Specified in 37 C.F.R. §1.703(f)

1. §1.703(a)

Applicants are in agreement with the USPTO determination of a period of 216 days under 37 C.F.R. §1.703(a).

Applicants respectfully request an additional period of adjustment equal to the number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee was paid, December 22, 2008, and all outstanding requirements were satisfied and ending on the date the patent was issued. *See*, 37 C.F.R. §1.703(a)(6).

2. §1.703(b)

The period of adjustment under 37 C.F.R. §1.702(b) begins on the day after the date that is three years from the filing date of the instant application, January 23, 2005, and ends on the day the patent is issued.

This period of adjustment does not include the period beginning on the date on which an RCE was filed, June 1, 2006. *See*, 37 C.F.R. §1.703(b)(1). This period of adjustment also does not include the period beginning on the date on which a Notice of Appeal was filed, December 8, 2005. *See*, 37 C.F.R. §1.703(b)(4). However, the periods on which the RCE was filed and the Notice of Appeal was filed overlap. Applicants have adjusted this period to the extent that such periods are not overlapping. *See*, 37 C.F.R. §1.703(f).

Thus, the effective period of adjustment under 37 C.F.R. §1.702(b) is 319 days, *i.e.*, from January 23, 2005, to December 8, 2005.

3. §1.703(c)-(d)

There are no relevant dates as specified under §§1.703(c)-(d).

4. §1.703(e)

The period of adjustment under 37 C.F.R. §1.703(e) begins on the day of filing of the Notice of Appeal, December 8, 2005, and ends on the day of a final decision in favor of the Applicants, in this instance, the final Notice of Allowance mailed on September 29, 2008. As discussed above, two periods of adjustment overlap. Applicants have adjusted this period to the extent that both periods are not overlapping.

5. §1.703(f)

The period of adjustment under 37 C.F.R. §1.703(f) is 535 days, *i.e.*, 216 days of “A delay” plus 319 days of “B delay.”

Applicants request that overlapping periods be determined in accordance with *Wyeth v. Dudas* (Case No. 07-1492, D.D.C. 2008) which held that the periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) overlap only if they occur on the same calendar day or days. Applicants note that *Wyeth v. Dudas*, is currently being appealed by the USPTO.

As discussed above, Applicants respectfully request an additional period of adjustment equal to the number of days, if any, under 37 C.F.R. §1.703(a)(6). Any such period of adjustment under 37 C.F.R. §1.703(a)(6) begins on January 23, 2005 and will not overlap with a period adjustment under 37 C.F.R. §1.702(b). This additional period does not include the period beginning on December 8, 2005.

Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704

The correct period of adjustment under §1.704(a) is 176 days, not 184 days as indicated by the Patent Term Adjustment History.

1. Response to Non-Final Office Action

The correct period of adjustment for the response to the non-final Office action is 8 days, not 16 days as determined by the Office. The non-final Office action was mailed November 21, 2007, and the response was filed February 29, 2008. The result is eight days of delay attributed to Applicants.

2. Summary

The total reduction period of adjustment for applicant delay is 176 days, not 184 days. The 176 days should be subtracted from the 535 days (“A delay” + “B delay”) as discussed above.

Assignees of the instant application note that a terminal disclaimer was filed on November 29, 2004, over the prior patent, US Patent 6,392,069 filed on July 8, 1998, and accordingly with an expiration date of July 8, 2018.

Patent Term Adjustment Determination

Applicants are entitled to 359 days of patent term adjustment, *i.e.*, [535 days (“A delay” + “B delay”)] minus [176 days (“applicant delay”)]. Applicants are also entitled to any period of adjustment under 37 C.F.R. §1.703(a)(6).

Please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Account No. 20-1430. Please charge any necessary additional fees or credit any overpayments to the Deposit Account No. 20-1430.

Based on the foregoing, Applicants respectfully request reconsideration of the patent term adjustment determination.

Respectfully submitted,



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